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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,870	02/28/2001	Xavier Forceville	569J US 3770	3493

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EXAMINER
PAK, JOHN D

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/763,870	Forceville et al.
Examiner	**Art Unit**
Pak, J.	1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Apr 18, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *23-43* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *23-33 and 35-43* is/are rejected.

7) ☒ Claim(s) *34* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claims 23-43 are pending in this application.

Claim 43 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 43 recites, "method of claim 42," but claim 42 is directed to a composition.

Claims 25, 29, 37, 39-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(1) Claims 25 and 37 are confusing. Said claims already depend on independent claims that recite specific mg/kg dose amounts. It is unclear how such specific dose is to be further "modulated according to a species 50% lethal dose (LD 50) in comparison with humans." What does this phrase mean relative to the dosage amounts recited in the independent claims?

(2) Claim 29 is unclear. What does it mean to "modulate more precisely different compartments of said systemic inflammatory reaction"? What is meant by "modulate" and what are "compartments" of a systemic inflammatory reaction?

(3) Claim 39 contains a misspelling of dose, "does."

(4) Claim 40 doesn't make sense. The first treatment is "administered during a time period between a first day to fourth day **of treatment** ..." (emphases added). How can there be a first or fourth day of treatment if this is the first treatment?

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 23, 25, 26, 27, 31 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chemical Abstracts 108:149240.

Chemical Abstracts 108:149240 explicitly discloses providing 0.2 mg/kg of selenium to calves challenged with infectious bovine rhinotracheitis virus (IBRV). Improved patient profile is disclosed.

Applicant's claim language, "severe acute attack of an inflammatory pathology causing an exacerbation of cytokine secretion," is broad enough to encompass IBRV, which is an acute infectious disease that causes systemic inflammation and cytokine secretion exacerbation. The claims are thereby anticipated or at the very least rendered obvious within the meaning of section 103(a). In re May, 197 USPQ 601, 607 (CCPA 1978); Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (Bd. Pat. App. & Int. 1993); In re Kirby, 40 USPQ 368 (CCPA 1939).

Claims 23, 25, 26, 27, 31 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chemical Abstracts 127: 171274.

Chemical Abstracts 127:171274 explicitly discloses providing 0.3 or 0.6 mg/kg/day selenium to chickens. After infection with infectious bursal disease (IBD), chickens that had the selenium treatment showed better profile and significantly lower mortality.

Applicant's claim language, "severe acute attack of an inflammatory pathology causing an exacerbation of cytokine secretion," is broad enough to encompass IBD, which is an immunosuppressive infectious disease that causes lesions and necessarily causes cytokine secretion exacerbation. The claims are thereby anticipated or at the very least rendered obvious within the meaning of section 103(a). May, 197 USPQ at 607; Novitski, 26 USPQ2d at 1390-91; Kirby, 40 USPQ 368.

Claims 23, 24, 25, 26, 28, 30, 31 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chemical Abstracts 129:134509.

Chemical Abstracts 129:134509 discloses treating young children under one year of age with pneumonia or bronchiolitis caused by respiratory syncytial virus with selenium supplementation. 1 mg sodium selenite was provided. It is noted that this amount of sodium selenite would meet applicant's claimed feature of 0.025-1 mg/kg for children under about 18.4 kg, which almost all children under one year of age are.

Applicant's claim language, "severe acute attack of an inflammatory pathology causing an exacerbation of cytokine secretion," is broad enough to encompass pneumonia or bronchiolitis

caused by respiratory syncytial virus, which would necessarily cause cytokine secretion exacerbation. The claims are thereby anticipated or at the very least rendered obvious within the meaning of section 103(a). May, 197 USPQ at 607; Novitski, 26 USPQ2d at 1390-91; Kirby, 40 USPQ 368.

Claims 41-43 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 98/33495.

WO 98/33495 explicitly discloses a dosage unit form, a pill, that contains 6.25 mg selenium aspartate and vitamin E (i.e. tocopheryl acetate). See page 5, Example 1; claims 1-2. It is noted that selenium aspartate, with one selenium atom, has MW 211.1, which would provide 2.3 mg selenium/pill. Selenium aspartate with two selenium atoms would provide 3.4 mg selenium/pill.

Even though the cited reference does not explicitly disclose the disclosed pill for administering to the same exact patients as applicant's claims, instant claims are directed to the composition per se and applicant's intent/preamble to use for patients that were not spelled out in verbatim by the cited reference does not militate against the fact that the same exact composition itself has been disclosed. Since the prior art composition contains the same exact composition ingredients and nothing in there would detract from the activity now claimed by applicant, the prior art composition must necessarily possess the properties claimed by applicant. The claimed invention is thereby anticipated or at the very least rendered obvious within the meaning of section 103(a).

Claims 23-33 and 35-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Zimmermann et al., Borner et al. and Chemical Abstracts 129:134509 in view of Medline abstract 89032644 and WO 98/33495.

Zimmermann et al. disclose providing 1 mg sodium selenite per day for 28 days for treating patients with systemic inflammatory response syndrome, SIRS (see pages 3-4).

Borner et al. disclose providing 200 μg selenium pentahydrate for patients weighing less than 15 kg and 500 μg for patients weighing 15-30 kg. The patients were children with severe inflammatory surgical diseases as well as widespread burns (see pages 17-18).

Chemical Abstracts 129:134509 discloses treating young children under one year of age with pneumonia or bronchiolitis caused by respiratory syncytial virus with selenium supplementation. 1 mg sodium selenite was provided. It is noted that this amount of sodium selenite would meet applicant's claimed feature of 0.025-1 mg/kg for children under about 18.4 kg, which almost all children under one year of age are.

Medline abstract 89032644 teaches that serum selenium concentration is significantly depressed during the acute state of bacterial or viral infection. The authors conclude that acute infections decrease serum levels of selenium "regardless of the infective agent."

WO 98/33495 explicitly discloses a dosage unit form, a pill, that contains 6.25 mg selenium aspartate and vitamin E (i.e. tocopheryl acetate). See page 5, Example 1; claims 1-2. It is noted that selenium aspartate, with one selenium atom, has MW 211.1, which would provide 2.3 mg selenium/pill. Selenium aspartate with two selenium atoms would provide 3.4 mg

selenium/pill. The disclosed pill is used to treat immunodeficiency mechanisms, infectious diseases of viral or bacterial origin, and those deriving from other external pathogens such as tuberculosis, diseases myelinic origin, etc. See from page 3, line 25 to page 4, line 8.

While the cited references do not expressly disclose all of the dependent claim features that are recited in applicant's claims, as well as a verbatim disclosure to use 0.025-1 mg/kg + subsequent treatments, the prior art as a whole suggests the same. It is well known and recognized that SIRS and various infectious states produce a state of significant selenium deficiency. Doses administered to a patient would depend on the severity of the selenium deficiency and toxicity or overdose concerns, but the prior art has nonetheless disclosed doses that are within applicant's specifically claimed range (Chemical Abstracts 129:134509; WO 98/33495). Because selenium is deficient, it would have been obvious to the ordinary skilled artisan to utilize any suitable selenium-containing physiologically acceptable compound, such as those recited in, for example, dependent claim 30, or a mixture thereof. Mode of administration is a matter of routine optimization for fast delivery or absorption, and incorporation of additional agents that would improve the recovery of the patient, such as antioxidants, antiinflammatory agents, etc., would have been suggested from the advantage of delivering multiple agents to control the inflammation and stabilize the patient. Adjustment of subsequent follow-up selenium supplementation would have been well within the skill of the ordinary skilled artisan, who would monitor the selenium drop and rise in response to treatment.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly suggested by the teachings of the cited references.

Claim 34 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Pak whose telephone number is (703) 308-4538. The Examiner can normally be reached on Monday through Thursday from 8:00 AM to 5:30 PM. The Examiner can also be reached on alternate Fridays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

JOHN PAK
PRIMARY EXAMINER
GROUP 1600